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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,293	08/06/2001	Timothy W. Conner	16517.254	7785
28381	7590	10/04/2006		
ARNOLD & PORTER LLP ATTN: IP DOCKETING DEPT. 555 TWELFTH STREET, N.W. WASHINGTON, DC 20004-1206			EXAMINER CLOW, LORI A	
			ART UNIT 1631	PAPER NUMBER

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/922,293

Applicant(s)

CONNER ET AL.

Examiner

Lori A. Clow, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10, 14-18, 21, 23 and 24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 14-19 is/are allowed.
- 6) ☒ Claim(s) 10, 21, 23, and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants' response, filed 13 July 2006, has been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 10, 14-18, 21, 23, and 24 are currently pending. Claims 1-9, 11-13, 19, 20, and 22 have been cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated transcription factor, does not reasonably provide enablement for a fragment of an isolated transcription factor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In *In re Wands* (8 USPQ2d 1400 (CAFC 1988)) the CAFC considered the issue of enablement in molecular biology. The CAFC summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or

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absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims.

In considering the factors for the instant claims:

a) In order to practice the claimed invention one of skill in the art must know a priori which fragments of SEQ ID NO: 1 are transcription factors or have transcription factor activity. For the reasons set forth below, this constitutes undue experimentation.

b) and c) The specification provides examples for a general description of homeobox transcription factors (page 31). The specification states generally that the present invention provides a substantially purified maize, soybean, or *Arabidopsis thaliana* transcription factor or fragment thereof selected from the group consisting of SEQ ID NOS: 1-3853 and that these are members of the homeobox transcription factor family (page 32). However, the specification provides no disclosure of specific fragments of SEQ ID NO: 1 that have transcription factor activity such that one of skill in the art would know how to make the instant invention. Rather, the specification discloses that SEQ ID NO:1 in Table A is homologous to GenBank accession number g642128, stating that there is 100% identity. However, an alignment (provided as an attachment to the Office Action herein), shows that SEQ ID NO:1 is only 83.4% identical to Genebank Accession Number g642128. Further, the alignment shows that the query sequence contains a MADS box at nucleotide position 24-194, matching nucleotides 77-247 of SEQ ID NO:1. However, the recited fragments of claims 10 and 21 are NOT limited to comprise at least the residues that are within the MADS Box domain and therefore, the specification is not enabling for all fragments of SEQ ID NO:1 to act as transcription factors. For example, the query sequence also contains a K box, an important homeobox transcription factor domain.

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However, SEQ ID NO:1 does not contain this domain. Without such active domains, one of skill in the art would not know how to make or use **any** fragment of SEQ ID NO:1 to function as a transcription factor.

d) The invention is drawn to an isolated transcription factor and fragments thereof.

However, the specification is not enabling for transcription factor fragments of SEQ ID NO: 1, as discussed above.

e) It would have been well known in the art that single or multiple substitutions or deletions can alter biomolecular function in many instances, albeit not all. In the absence of any factual evidence that characterizes the structural and functional components of a biomolecule, the effects of these changes are largely unpredictable. In some cases mutations will lend no effect, as in silent mutations and in others, up regulation or down regulation may occur. There have been several publications documenting the unpredictability of the relationship between sequence, structure and function, even though it has been found in some cases that conserved biomolecules have related functions after significant physical research. Such research, however, is lacking in the current specification.

The prediction of gene function and protein activity based on alignments is highly unpredictable. Even the term “gene function” has a variety of definitions that only make sense in context. Bork et al. (Bork et al. (1998) JMB 283 :707-725: PTO-1449) discuss the many differing definitions that “gene function” or “protein function” can have. Enzymatic activity, activity within a pathway, and potential activity with or on a partner protein, such as in receptor activity, are possible definitions, and Bork et al. note that these activities are only being predicted qualitatively, and not necessarily accurately. Other definitions which Bork et al. note can be

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predicted with even less certainty include expression patterns, **regulation** (functional link), kinetic properties, localization and concentration effects. Bork et al. state that most functional features of the respective proteins will remain hidden, despite attempts at prediction of those features. Furthermore, this information transfer from well studied proteins to uncharacterized genes has to be done carefully since (i) similar protein structures or functions (in particular in important details such as recognition loops (as in receptor domain loops) and (ii) the annotation of the database protein might be incomplete or even wrong (page 708).

f) The skill of those in the art of molecular biology is high.

g) The prior art indicates that “[p]rediction of function from sequence is a considerably more complex enterprise than a simple sequence database search which represented the entire repertoire or tools a few years ago.” (Bork et al., page 721) This indicates that more than a simple alignment between one or more protein sequences at one or more residues is required to even suggest said proteins may have similar function because of conserved sites. It is noted that SEQ ID NO: 1 is assumed to have transcription factor activity based on a region with EXACT identity to a known MADS box in a protein known to be a transcription factor. Fragments of SEQ ID NO: 1 are not limited to comprise the MADS box region, nor to comprise any other known conserved domain necessary for transcription factor activity.

h) The claims are broad because they are drawn to any and all fragments of SEQ ID NO:1. The skilled practitioner would first turn to the instant specification for guidance. However, the instant specification does not provide specific guidance to make and/or use fragments of SEQ ID NO: 1, as it is not disclosed whether any fragment alone is, in fact a transcription factor. As such, the skilled practitioner would turn to the prior art for such

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guidance, however, the prior art shows that alterations in sequence (i.e. deletions such that fragments result) are not predictable. Finally, said practitioner would turn to trial and error experimentation to determine whether said altered sequences (i.e. fragments) are indeed similar or have similar activity through the methods discussed by Bork et al, including substantial bench research. Such represents undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 21 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites “is within a recombinant nucleic acid construct”. It is unclear what further limitation of the protein is intended, as the protein is the same regardless of where the encoding nucleic acid resides. Clarification is requested.

Claim 24 recites “said construct is inserted into a plant genome”. This limitation is unclear because it appears to be a method step. Perhaps applicant intends the claim to state that the construct “is comprised within” a plant genome. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by GeneBank

Accession Number D30807 (8 March 1995; recited previously in the Office Actions mailed 9/29/05 and 9/9/03). Upon further consideration of the claims, this rejection is hereby re-instated.

Claims 10 and 21 continue to recite fragments of SEQ ID NO:1. D30807 contains 267 consecutive nucleic acids corresponding to nucleic acids 54-320 of SEQ ID NO:1, thus meeting the limitations of the fragments recited in claims 10 and 21.

Claims 10 and 21 are rejected under 35 U.S.C. 102(b) as being anticipated by GeneBank Accession Number AA728430 (5 January 1998; recited previously in the Office Action mailed 9/29/05). Upon further consideration of the claims, this rejection is hereby re-instated.

AA728430 contains 256 consecutive nucleic acids corresponding to nucleic acids 65-320 of instant SEQ ID NO:1, thus meeting the fragment limitations of claims 10 and 21.

Conclusion

Note: Claims 21 and 23 contain claim language that is not entirely clear, but does not render the claims indefinite. The Examiner suggests amending the claims to recite “is comprised within” for better clarity.

Claims 10, 21, 23, and 24 are rejected.

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The outstanding rejections under 35 USC 101 (Utility) have been withdrawn in view of sequence alignment with the sequence in the prior art of GeneBank Accession Number D30807, which indicates that SEQ ID NO: 1 contains a transcription factor MADS box at nucleotide positions 77-194.

Claims 14-18 are allowable, as the prior art does not teach or fairly suggest a substantially purified nucleic acid molecule comprising the nucleic acid sequence having the nucleic acid sequence of SEQ ID NO:1 or the complete complement thereof or that shares between 100% and 90%, 100% and 95%, 100% and 98%, or 100% and 99% sequence identity with SEQ ID NO:1. The claims have utility, as they are drawn to a transcription factor with known sequence comparison to a sequence comprising a MADS box domain.

Inquiries

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central Fax Center Number is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lori A. Clow, Ph.D., whose telephone number is (571) 272-0715. The examiner can normally be reached on Monday-Friday from 10 am to 6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete

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service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

September 28, 2006

Lori A. Clow, Ph.D.

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Lori A. Clow

Marjorie A. Moran

10/2/06

MARJORIE A. MORAN
PRIMARY EXAMINER